



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

June 14, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edna Moore, Radiology Manager
Women's Diagnostic Center
133 Glenn Rd.
Gamer, North Carolina 27529

Inspection ID: 2189250001

WARNING LETTER
99-ATL-19

Dear Ms. Moore:

Your facility was inspected on May 19, 1999, by a representative of the North Carolina Department of Environment and Natural Resources, Division of Radiation Protection, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The interpreting physician did not meet the requirement of being certified by a FDA recognized board or having the alternative of 2 months training in the interpretation of mammograms:

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, the following Level 2 and Level 3 noncompliances were listed on the inspection report provided to you at the close of the inspection.

Level 2 noncompliances:

The following interpreting physicians did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6-month period):

The following interpreting physicians did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period:

The following interpreting physicians did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography:

Level 3 noncompliances:

The QA program is inadequate. For site Women's Diagnostic Center, the missing or incomplete item(s) are listed below:

Personnel responsibilities.

The repeat analysis QC is not adequate for site Women's Diagnostic Center because there was no evaluation system to determine cause(s) of repeats.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may initiate regulatory action without further notice. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a state from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent state requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- Sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed.

Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Enforcement
60 8th St., NE
Atlanta, GA 30309

With a copy to:

North Carolina Department of Environment and Natural Resources
Division of Radiation Protection
3825 Barrett Drive
Raleigh, NC 27609-7221

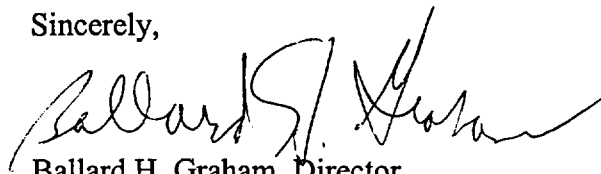
and

Thomas Clarida
U.S. Food and Drug Administration
5701 Executive Center Drive, Suite 104
Charlotte, NC 28212

(NOTE: If phantom image is required for corrective action, please submit to North Carolina Department of Environment and Natural Resources, Division of Radiation Protection.)

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704/344-6116.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham", is written over the typed name.

Ballard H. Graham, Director
Atlanta District